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SAGES-AHPBA 2025 guideline for the surgical management of bile duct injury following cholecystectomy

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Abstract

Background Bile duct injury (BDI) following cholecystectomy is a complication associated with significant morbidity and mortality. This guideline addresses timing and type of repair following injury to improve patient outcomes and surgical decision-making.

Methodology A systematic review was carried out, including a literature search up to December 31, 2024 addressing four key questions regarding the definitive repair of BDI following cholecystectomy. The findings were subsequently presented to a panel of surgeons from both the Society of American Gastrointestinal and Endoscopic Surgeons and the American (SAGES) and the Americas Hepato-Pancreato-Biliary Association (AHPBA). Subject matter experts then used the GRADE methodology to develop evidence-based recommendations.

Results A conditional recommendation, with low certainty of evidence, in favor of delayed (> 6 weeks) versus early definitive repair (< 6 weeks) of BDI was made. A conditional recommendation for either minimally invasive or open repair was made based on very low certainty of evidence. A conditional recommendation was made for either the nonoperative or operative definitive repair of BDI based on very low certainty of evidence. Finally, a conditional recommendation was made for either hepaticoduodenostomy or hepaticojejunostomy as a bilioenteric anastomosis approach following BDI based on very low certainty of evidence.

Conclusion These recommendations provide guidance for the approach to repair of BDI following cholecystectomy according to the existing literature and expert input. The panel also highlighted evidence gaps to support future research for a stronger evidence base around BDI repair.

Keywords Guideline · Bile duct injury · Cholecystectomy · Endoscopy · Interventional radiology · Hepaticojejunostomy · Hepaticoduodenostomy

Abbreviations

BDI	Bile duct injury
MIS	Minimally invasive surgery
HJ	Hepaticojejunostomy
HD	Hepaticoduodenostomy
RCT	Randomized controlled trial
RR	Risk ratio
OR	Odds ratio
CI	Confidence interval
EtD	Evidence to decision
GRADE	Grading of recommendations, assessment, development, and evaluations
KQ	Key questions
PICO	Population, intervention, comparison, outcome
AHPBA	American Hepato-Pancreato-Biliary Association
SAGES	Society of American Gastrointestinal and Endoscopic Surgeons

Extended author information available on the last page of the article

Background

Bile duct injury (BDI) is a known, severe complication following cholecystectomy. It is associated with high morbidity and mortality making optimal recognition and timing as well as type of repair of utmost importance to improve quality of

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life and survival [1–3]. In this guideline, the timing of surgical reconstruction, types of surgical reconstruction, and nonoperative procedural options following BDI is investigated to improve patient outcomes and surgical decision-making.

Interpretation of strong and conditional recommendations

All guideline recommendations were proclaimed as "strong" or "conditional". The phrase "the guideline panel recommends" is used for strong recommendations, and "the guideline panel suggests" for conditional recommendations, as per the GRADE approach [4]. A conditional recommendation signals that the benefits of adhering to a recommendation probably outweigh the harms but contains uncertainty. This uncertainty may be due to a lack of high-quality evidence or variability in how individual patients value the outcomes of interest.

How to use these guidelines

These guidelines are primarily intended to aid surgeons in decision making for the definitive repair of BDI following cholecystectomy. They are also intended to educate, inform policy and advocacy, and to define future research needs. Clinical decision making is multifaceted, and these guidelines are intended to suggest, but not mandate, an acceptable approach to surgical management. These guidelines can also be used by patients as a basis of discussion with their treating surgeon.

Summary of key questions (KQ) and associated recommendations

KQ 1: Should patients with a known bile duct injury following cholecystectomy undergo early repair or delayed definitive repair?

Recommendation: The panel suggests delayed repair (greater than 6 weeks) by an experienced surgeon in HPB pathology for the management of BDI following cholecystectomy. *(conditional recommendation, very low certainty of evidence)*

The current recommendation supports temporizing measures in a patient who presents within 6 weeks of their index operation, including intraoperative detection, with BDI if there is no hepatobiliary surgery expert available at their local facility

KQ 2: Should patients with a known bile duct injury undergo MIS repair or open definitive repair?

Recommendation: The panel suggest either MIS or open definitive repair by an experienced surgeon in HPB pathology for patients undergoing surgery with known BDI. *(conditional recommendation, very low certainty of evidence)*

MIS repair is preferred in those patients who are stable, with favorable anatomy, in those with high BMI or obesity. This should only be performed by surgeons experienced in both MIS and HPB surgery. Open surgery is preferred in those that are unstable, have high and/or complex injuries, have an open incision, and those who have suspected severe inflammation. Long-term outcomes data is required to better understand this question. *(Expert opinion)*

KQ 3: Should patients with a known bile duct injury undergo definitive operative management or nonoperative management?

Recommendation: The panel suggests either definitive operative management or nonoperative management for amenable injuries with expertise available. *(conditional recommendation, very low certainty of evidence)*

KQ4: Should patients with known bile duct injury undergoing surgery be repaired using hepaticoduodenostomy or hepaticojejunostomy?

Recommendation: The panel suggests either hepaticoduodenostomy or hepaticojejunostomy with the decision dependent upon location of injury and expertise of the surgeon. *(conditional recommendation, very low certainty of evidence)*

Long-term outcomes data is required to better understand this question.

Description of the health problem

Major bile duct injury (BDI) during cholecystectomy is a severe complication with rates of injury during laparoscopic cholecystectomy ranging between 0.04 and 0.6% [5–13]. The consequences can be devastating with high morbidity and mortality. Death in these patients is reported anywhere from 3 to 20% depending on timing, expertise, and cohort selection [2, 3, 13]. For survivors, these injuries contribute to a significant decrease in quality of life, decreased work productivity and need for disability benefits [3, 13, 14]. Even with appropriate treatment there can be long term morbidity secondary to stricture which often requires further treatment and hospital stay [3, 13]. This occurs in about 10% of patients [3, 14]. For this reason, follow-up after surgical treatment of these patients is recommended for at least 10 years post-operatively [14]. Appropriate treatment plans in this patient population are therefore pivotal in their survival and outcome improvement.

Therapeutic decision making and success is largely dependent on type of injury, concomitant vascular injury, control of sepsis, timing of diagnosis or referral, and expertise availability [3, 13–15]. The type of injury can be stratified using the well-known Strasberg classification system whereby five groups of injury exist (A to E) [16, 17]. Class A is the least severe and represents a bile leak from the cystic duct or small ducts in the liver bed. Class E is generally regarded as the most severe as it is a circumferential injury to a major bile duct with loss of continuity and is further subclassified into E1–E5 [13, 16, 17]. Concomitant vascular injury is not included in this system, however, and is reported as present in 26–32% of these

patients [14]. Timing of therapy is dependent on diagnosis, with only 15–30% of injuries diagnosed intraoperatively [18] Finally, it has been well demonstrated that outcomes are improved with specialty care at a tertiary center with surgeons and physicians well versed in hepatobiliary intervention [13, 14].

Historically, nonoperative management was not an option for higher grade injuries and was mainly used for minor leaks or strictures. For example, endoscopic treatment was often employed in these patients, but only when the duct was in continuity with the rest of the biliary tree, making Type B, C, E injuries unlikely to be endoscopically treated. More recently, non-surgical treatments have become more sophisticated and their role continues to evolve with an increasing use in BDI management [13, 14, 19]. In fact, some specialized centers have been able to employ endoscopic treatment in higher grade injuries as well [20].

Surgical management for BDI often requires bilioenteric anastomosis. Hepaticojejunostomy is currently the favored technique, having the most long term supporting data [13, 21–23]. Hepaticoduodenostomy is an alternative technique for BDI although less commonly used [24]. Specifically, hepaticoduodenostomy is a technically more straight forward surgery, more physiological, and facilitates easier postoperative endoscopic access should complications arise. However, its use is dependent on appropriate anatomy.

A SAGES multi-society guideline was created in 2020 for the prevention of BDI with safe cholecystectomy strategies and referral of patients with suspected or confirmed BDI to an experienced hepato-pancreato-biliary (HPB) team [25]. While prevention of BDI is the best-case scenario, in this guideline we aim to compare the aforementioned modalities of treatment for BDI following cholecystectomy using the currently available literature, patient input, and surgical expert judgement.

Methods

The creation of these guidelines followed the SAGES Guidelines Development Standard Operating Procedure [26]. The guideline panel used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to evaluate the certainty of the evidence [27, 28] and the GRADE Evidence to Decision (EtD) framework to deliberate and formulate recommendations [29–31], through the GRADEpro guideline development tool [32]. Reporting of this guideline was structured as per the Essential Reporting Items for Practice Guidelines in Healthcare (RIGHT) and the Appraisal of Guidelines for Research & Evaluation (AGREE) checklists [31, 33–35]. Organizational approval, review and plans for updating were also established.

Scope, population and target users

The primary focus for this guideline was to determine best practice for repair of bile duct injuries (BDI) following cholecystectomy. The population of interest are adult patients with a major BDI during cholecystectomy. Major BDI was defined using the Strasberg criteria, grades B through E [16]. The target audience for this guideline is composed of surgeons, surgical trainees, institutional stakeholders, and patients. Policy makers and insurance providers interested in this guideline include those involved in delivering local, national, and international health care services supporting the comprehensive diagnosis and treatment of pathologies requiring surgical intervention or evaluating the direct and indirect benefits and risks related to repair approaches for BDI. This guideline took a patient-centered perspective with an international scope. All recommendations presented in this guideline should be implemented by experienced surgeons in hepatobiliary pathology. The benefit of this has already been demonstrated previously [25, 36–38].

Guideline panel organization

International experts across several surgical subspecialties were invited to participate in the guideline panel from the SAGES Guidelines Committee, the SAGES Hepato-pancreato-biliary/Solid Organ (HPB/SO) Committee, and the American Hepato-Pancreato-Biliary Association (AHPBA). All panel members were experienced surgeons. Three patient partners provided their values, preferences and opinions surrounding questions and outcomes. A summary of their input is provided under Values and Patient Perspective. A methodologist (I.V.) and the SAGES Guidelines Committee Fellow (E.C.C.) participated in the panel as non-voting members. They have extensive guideline development experience and facilitated appraisal of the evidence and formulation of the recommendations.

The panel reviewed evidence tables, created with the assistance of the guideline methodologist, populated by the systematic review results and voted on components of the EtD framework to reach final recommendations [29–31]. Both the evidence tables and EtD tables were compiled using GradePro [32].

Guideline funding & declaration and management of competing interests

SAGES provided funding for the methodologist, the systematic review statistician, the librarian, and partial salary support for the guidelines committee fellow. Part of this funding came from a SAGES Education & Research Foundation grant. None of these members were voting members of the guideline panel.

All voting members of the panel participated voluntarily without monetary compensation. Industry did not provide any financial support for or input on the development of these guidelines. All guideline panel members completed ICMJE disclosure forms [39]. Each disclosure form was reviewed and considered for pertinent conflicts of interest [40]. None of the members had a conflict of interest that prevented them from participating in the guideline discussion [41].

Selection of questions and outcomes of interest

The primary focus for this guideline was to determine best practice for definitive repair of BDIs following open or minimally invasive cholecystectomy. Panel members developed key questions in consultation with the guideline methodologist according to the patient-intervention-comparator-outcome (PICO) format. Several iterations were created with the help of the project leads, the methodologist, and fellow until a final version was agreed upon.

Key questions

- KQ 1: should patients with a known bile duct injury following cholecystectomy undergo early repair at less than 6 weeks or delayed definitive repair at greater than 6 weeks?
- KQ 2: should patients with a known bile duct injury undergo MIS repair or open definitive repair?
- KQ 3: should patients with a known bile duct injury undergo definitive operative management or nonoperative management?
- KQ4: should patients with known bile duct injury undergoing surgery be definitively repaired using hepaticoduodenostomy or hepaticojejunostomy?

Outcomes specific to each key question were determined a priori based on what the panel thought key stakeholders, surgeons, and patients would consider relevant. Following the GRADE approach, outcomes were distributed to the panel members and they were asked to rate their importance on a scale from 1 to 9, with ratings of 7 to 9 representing critical outcomes, 4 to 6 representing important but not critical outcomes, and 1 to 3 representing unimportant outcomes [4] Only important and critical outcomes were used in decision-making for these guidelines. Return to the OR, mortality (90-day), morbidity (Clavien Dindo III&IV), quality of life, and stricture/cholangitis/leak were voted critical outcomes. Re-intervention for failure (endoscopic and radiologic), length of stay, and conversion to open were voted important. Patients were consulted to provide their value on the outcomes selected and to provide feedback on the guideline.

Determining utility values for dichotomous outcomes

To provide a more streamlined and transparent method to determine the balance of effects in panel discussions, utility values were used prior to the meeting to calculate coefficients for each outcome. Panel members were asked to rate the utility of each outcome for KQs 1–4 on a cardinal scale from 0 to 1 in increments of 0.1, with 0 being death and 1 being the best possible health state [42, 43]. Utility values are preference weights, where preference can be equated to value or desirability [42, 44] and are also dependent on the stakeholder, their personal experience, and the clinical question being considered. The mean utility value was calculated for each outcome after panel members voted.

After the certainty of evidence was determined using GRADEpro GDT [32], the utility values were then converted to absolute risk difference thresholds according to the equation *absolute risk difference = [coefficient/(1 − utility)] × 1000*. We used evidence-based, predetermined cutoff coefficients to determine the absolute risk difference decision thresholds for each outcome [45]:

- 0.0135 coefficient for trivial-to-small effect threshold
- 0.0321 coefficient for small-to-moderate effect threshold
- 0.0625 coefficient for moderate to large effect threshold

These cutoffs were used to determine imprecision in the pooled data for each outcome (see *Evidence Review and Synthesis)*. The absolute risk difference was used to determine the coefficient for each outcome using the equation *Coefficient = Absolute Risk Difference * (1-Utility)*. We aggregated these values for each outcome, with a positive value given to those that were under "desirable outcomes" and a negative value to those that were "undesirable outcomes" depending on the key question being evaluated. The resulting numerical coefficient for the body of data as well as the direction and effect size for the Balance of Effects domain in the EtD tables were determined using this calculated, aggregated coefficient value. The calculated value was compared to the predetermined coefficients described above to determine whether the effect size was trivial, small, moderate, or large. These calculations and values were presented to the panel to ensure that they were appropriate.

Search strategy and eligibility criteria

PubMed, CINAHL, Embase, and Cochrane Library were searched through December 31, 2024 to identify randomized controlled trials and non-randomized comparative studies. Additional searches were performed in clinicaltrials.gov to identify eligible ongoing trials.

Two independent reviewers screened the retrieved records for eligibility. Studies were included if they were published in the English language, were comparative cohort or RCT studies, included patients with Strasberg B–E injury, and excluded patients who had previous attempts at definitive repair (limit for exclusion: > 10%). We considered single arm studies with more than 10 patients only in the absence of comparative studies (i.e., KQ2 to 4). Exclusion criteria included Strasberg A injuries, no English text available, case reports, editorials, and reviews.

Data extraction and risk of bias

Extraction of all predetermined outcome data from the selected studies was conducted for each KQ by two independent reviewers, followed by consensus and risk of bias assessment. Study quality was assessed using the Cochrane Risk of Bias 2.0 and Newcastle Ottawa Scale for randomized and non-randomized studies, respectively [46, 47].

Evidence synthesis and meta-analyses

A systematic review of the evidence informed the guideline recommendations and was performed according to the Cochrane Handbook for Systematic Reviews of Interventions [48]. Reporting of the systematic review was informed by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) checklist [49]. A brief summary of methods is provided in this manuscript. For more detailed methods, refer to the systematic review and meta-analysis, published separately [50].

All included studies were summarized narratively, and when comparative evidence was available, random effects models meta-analyses were performed. We assessed heterogeneity with the I^2 statistic [51]. When randomized and non-randomised comparative evidence was available, we conducted and presented separate analyses. Certainty was rated as very low, low, moderate, or high [54].

Determining certainty of evidence

For each outcome, certainty of evidence (also called quality of evidence) was determined by evaluating the risk of bias, inconsistency, indirectness, and imprecision of the included studies [52–55]. Too few studies were available to assess publication bias. The level of certainty was downgraded if there were concerns in any of these domains. Methods outlined in the GRADE handbook were used to judge the certainty of evidence for each outcome of interest [4]. Table 1 presents the certainty of evidence levels and their interpretation.

Evidence summary and preparation

Results from the systematic review and meta-analysis were uploaded to GradePRO-GDT to facilitate evidence appraisal and panel decision-making. The evidence directly compared the intervention and comparator for the respective KQ. Indirect evidence was not deemed necessary and omitted in favor of direct evidence. Evidence tables were created (Appendix A) [32]. The highest level of data available was used for the tables; less rigorous data that addressed the same outcomes were reviewed but not used in decision making. In brief, the guidelines fellow and methodologist judged the certainty of the body of evidence, and they were revised after receiving input from panel members.

The data contributing to decision making for each key question are presented by outcome with the number of studies, total number of participants, certainty of the evidence, statistical method used to evaluate the data with its associated confidence interval (CI), and the absolute risk difference with its associated CI. Odds ratio (OR) was used for dichotomous outcomes and mean difference (MD) and standard mean difference (SMD) for continuous outcomes. The standard mean difference was used rather than mean difference if the rating scales used were not identical between studies. The absolute risk difference for binary outcomes is reported as either more or fewer number of patients/cases occurring in the intervention group relative to the comparator group out of 1000.

EtD and formulation of recommendations

Summary of findings tables reporting the critical and important outcomes were imported into the Evidence-to-Decision (EtD) table for each KQ in the GRADE-PRO GDT [32]. The EtD framework tables compile evidence on effectiveness and safety (GRADE profile), benefit-risk balance

Table 1 GRADE certainty of the evidence and its interpretation

Certainty level	Interpretation
High	The authors have high confidence that the true effect is close to the estimated effect
Moderate	The authors believe that the true effect is likely to be close to the estimated effect
Low	The true effect may be substantially different from the estimated effect
Very low	The true effect is likely to be substantially different from the estimated effect

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(beneficial versus harmful outcomes, including adverse events or hepatotoxicity), values and preferences, resource use, cost-effectiveness, impact on health equity, acceptability, and feasibility [56]. Cost was considered by the panel when creating the recommendations but did not influence overall decision making as no formal cost analysis was performed. Expert opinion was documented when evidence-based recommendations could not be made due to absent or inconclusive evidence.

After discussing the available evidence for each of these components, as well as pertinent additional considerations noted by the panelists based on interpretation of the evidence or expert experience, the panel voted on each component of the EtD table. The panel's judgments on each factor were recorded, followed by voting and consensus. We defined agreement as ≥ 80% of votes achieved in any EtD judgement and for the final recommendations. (Appendix B). Recommendations were formulated when > 80% consensus was achieved and were classified as strong or conditional (either for or against), depending on the overall GRADE-EtD judgment. Table 2 outlines these definitions and implications.

Values and preferences

As this guideline took a patient-centered perspective, the panel members used their collective experience to make judgements about patient values and preferences. In addition, three patient partners provided input on the outcomes and overall decisions.

Guideline document review

Once the guideline was reviewed and edited by all panel members, it was submitted to the SAGES Board of Governors for approval. It was published online (https://www.sages.org) for two weeks of public comment prior to final submission and publication. The feedback received from members and the public was considered to revise the guideline content.

Values and patient perspective

Three patient partners (AL, AT, RV) who have undergone interventions for BDI following cholecystectomy were interviewed for their opinions on outcomes, values, and overall input regarding BDI treatment. All were young females with diagnosis of injury 1–2 weeks post cholecystectomy who differed in regards to injury severity, sepsis, and repair. AL underwent early robotic hepaticoduodenostomy. AT underwent initial robotic damage control surgery with wide drainage and delayed robotic bilioenteric repair. RV underwent endoscopic stent placement as well as stent replacement 3 months post procedure which was complicated by pancreatitis. Her stent was removed 6 months from the first procedure. All three patients strongly supported preserving quality of life and minimizing re-interventions, and therefore overall recovery time, as the most important outcomes. They also noted that all the outcomes in this guideline were important and did not have anything to add. However, RV stated that perhaps Clavien Dindo II complications should also be considered, as pancreatitis was the most debilitating part of her recovery despite being treated conservatively. In fact, RV reflected that she would have preferred surgery had it meant fewer procedures, even if the initial recovery was longer. AL and AT would both recommend MIS repair when possible. While our patient partners provided invaluable feedback, it is important to acknowledge that their input is not reflective of all patient perspectives.

Table 2 Implications of the strength of recommendations according to different guideline users

Strength of the recommendation	Strong	Conditional
Clinicians	Most individuals should receive the recommended course of action. Adherence to this recommendation could be used as a quality criterion or performance indicator. Formal decision aids are not likely to be needed to help individuals make decisions aligned with their values and preferences	Different choices may be appropriate for different patients, and clinicians must assist each patient in making a management decision consistent with their values and preferences. Decision aids may be useful to help individuals make choices aligned with their values and preferences. Clinicians should expect to spend more time in shared decision-making
Patients	Most people in this situation would want the recommended course of action, and only a small proportion would not	While many would prefer the suggested course of action, a substantial number would not
Policymakers/health system decision-makers	The recommendation can be adopted as policy in most situations, including as a basis for performance indicators	Policymaking will require extensive deliberation and stakeholder engagement. Policies are more likely to vary across regions. Performance indicators should reflect the need for proper deliberation on available management options

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Recommendations

KQ 1: Should patients with a known bile duct injury following cholecystectomy undergo early repair or delayed definitive repair?

Recommendation: The panel suggests delayed repair (greater than 6 weeks) by an experienced surgeon in HPB pathology for the management of BDI following cholecystectomy. *(conditional recommendation, very low certainty of evidence)*

The current recommendation supports temporizing measures in a patient who presents within 6 weeks of their index operation, including intraoperative detection, with BDI if there is no hepatobiliary surgery expert available at their local facility

Summary of the evidence

We included one RCT and seven observational studies were included. The RCT [57] included patients with previous attempted repair, however, they made up less than 20% of each group and were evenly distributed so ultimately were deemed appropriate for inclusion. The early repair cohort included patients with and without sepsis and had an unexplained dropout rate of 17% in the septic cohort making this study high risk of bias. The median follow-up time was about two years for all outcomes except quality of life which had only 3-month follow-up. Length of stay was defined as the total hospital stay across their entire follow-up in days.

All observational studies [58–64] had high risk of bias due to a combination of selection bias and lack of statistical controls for potential confounding variables. This guideline prioritized the randomized evidence to support the recommendation unless evidence for a specific outcome was not available from RCTs. Despite RCT data available for stricture, observational data were used for this outcome because of a longer follow-up period. Two of the four observational studies reported outcomes over five years, which is critical for this outcome.

Initially, studies that included intraoperative detection of BDI with repair under the same anesthesia event were included, however, this created significant heterogeneity in the early group. For this reason, a subgroup analysis was performed for intraoperative repair, when available studies were excluded if more than 20% of their early cohort had intraoperative repair with no separation of outcomes. Clinically, separating this cohort is also important because the tissue in the area of injury has not been compromised from ongoing sepsis and fibrosis making intra-operative repair distinct from those that are several days out from the index operation. Goyman et al. and Iannelli et al. provided separate immediate repair outcomes data [60, 61]. A subgroup analysis was performed with that data and was reviewed by the panel. Finally, all studies were conducted at tertiary referral centers and/or were performed by surgeons with expertise in hepatobiliary surgery.

Benefits

Early repair was better than delayed repair across the following outcomes:

Length of stay (1 RCT, 277 participants, low certainty of evidence, mean difference 6 days lower, CI [8.5 lower to 3.5 lower]).****

The combined magnitude of these effects was determined to be trivial.

Harms and burden

Early repair (< 6 w) was worse than delayed repair (> 6 w) across the following outcomes:

- Quality of Life (1 RCT with 277 participants, moderate certainty of evidence, mean difference 0.03 lower, CI [0.07 lower to 0.01 lower])
- Mortality (1 RCT with 277 participants, very low certainty of evidence, OR 1.74 CI[0.36–8.38], 17 more per 1000, CI [15 fewer to 147 more])
- re-intervention—surgery (4 observation studies with 1380 participants, very low certainty of evidence, OR 3.31, CI [1.56–7.03], 93 more per 1000, CI [24 more to 211 more])
- re-intervention—endoscopic/radiologic (1 RCT with 277 participants, very low certainty of evidence, OR 1.35, CI [0.72–2.51], 53 more per 1000, CI [48 fewer to 188 more])
- Stricture (4 observational studies with 222 participants, very low certainty of evidence, OR 7.41, CI [2.07–26.52], 157 more per 1000, CI [30 more to 421 more])
- Morbidity—Clavien Dindo III-IV (1 RCT with 277 participants, very low certainty of evidence, OR 1.14, CI [0.64–2.02], 27 more per 1000, CI [80 fewer to 159 more])
- Leak (1 RCT with 277 participants, very low certainty of evidence, OR 2.56, CI [0.73–8.99], 51 more per 1000, CI [9 fewer to 216 more])
- Cholangitis (1 RCT with 277 participants, very low certainty of evidence, OR 1.97, CI [0.42–9.32], 22 more per 1000, CI [14 fewer to 163 more])

The combined magnitude of these effects was determined to be large.

Certainty of evidence

The overall certainty of evidence was very low.

Evidence discussion to final recommendation

Evidence tables and EtD judgements can be found in Appendix A and B, respectively. The final recommendation was made with consideration of patient values, global acceptability and feasibility. Late repair is preferred and considered likely acceptable and feasible to other stakeholders by the panel provided the hospital center has the means to control sepsis while waiting for definitive repair. This could be done by surgical wide drainage if other nonoperative options are unavailable.

One must consider several key issues when making decisions about timing for definitive operative reconstruction for BDI. The very low certainty of evidence makes it critical to consider each patient on an individual basis, although the data very clearly favor delayed operative repair (> 6 weeks). Circumstances in which delayed surgery may be of additional benefit are those with highly severe injuries and concomitant vascular injuries. However, it may not be possible to delay repair in patients with uncontrolled sepsis and in facilities that lack interventional radiology (IR) and/or therapeutic endoscopy (even if surgical expertise is available).

In certain situations, it may be favorable to perform an early repair (< 6 weeks), particularly if the surgeon is highly skilled at reconstruction, the injury type has been well defined, intra-abdominal sepsis is controlled/eradicated, and expertise for possible adjunct procedures are available should further intervention be required. This is especially true if the injury is discovered during the index operation or within a week following injury.

The availability of IR and therapeutic endoscopy is critical for decision making as it allows for more flexibility in diagnostic work up and management. These procedures may provide control of sepsis to allow for delayed repair and can be a useful adjunct after repair should complications arise. Expertise in hepatobiliary surgery is also an important consideration as this is a known predictor of improved outcomes following treatment of BDI. The current recommendation supports temporizing measures, e.g. drainage, PTHC, stent placement in a patient who presents within 6 weeks of their index operation with BDI if there is no hepatobiliary surgery expert available at their local facility. This allows time for the patient to be transferred to another facility without comprising outcomes. If the injury is detected at the index operation, safe temporizing measures include wide drainage for control of sepsis and biliary diversion if possible.

A subgroup analysis was performed for immediate intraoperative repair and favored delayed repair, although many of these repairs were performed by general surgeons rather than hepatobiliary surgeons. If expertise is available, immediate intraoperative repair could be of benefit in certain patients.

The RCT in this analysis excluded patients with concurrent vascular injury. We do not suspect that this would change the direction of the data toward early repair, as delayed repair would allow time for revascularization of the CBD, reducing the risk of postoperative stricture. Other subgroups that should be taken into consideration as potential confounders to the data are those with sepsis, those undergoing repair within one week of injury, those undergoing immediate intraoperative repair, those with high severity of injury, and those with a failed previous repair.

Conclusion

The panel suggests that delayed repair (> 6 weeks) be performed over early repair (< 6 weeks) in patients with BDI. Early repair may be considered for a select group of patients. Surgical expertise, IR and advanced endoscopy availability, severity of injury, and presence of sepsis are some of the factors that should be taken into account when making a decision for timing of surgery.

Future research recommendations

Future research should first standardize and clearly define time points- immediate v early v delayed. Exploring more granular time periods (e.g., reconstruction in less than one week) should also be considered. Additional topics of study include the timing of repair in those who have failed previous repair, outcomes among patients with varying injury severity, and outcomes after concomitant vascular injury. More RCTs would be ideal, although large observational studies with propensity score matching or multivariate analysis would also be of use considering the limited amount of data available and the high risk of bias present in the only RCT available. Maintaining a national or international registry of BDIs is encouraged to help facilitate further studies. Finally, a nomogram risk calculator tool to facilitate decision-making between early and late repair based on patient factors and resources available would be of great benefit and may provide standardization.

KQ 2: Should patients with a known bile duct injury undergo MIS repair or open definitive repair?

Recommendation: The panel suggest either MIS or open definitive repair by an experienced surgeon in HPB pathology for patients undergoing surgery with known BDI. *(conditional recommendation, very low certainty of evidence)*

MIS repair is preferred in those patients who are stable, with favorable anatomy, in those with high BMI or obesity. This should only be performed by surgeons experienced in both MIS and HPB surgery. Open surgery is preferred in those that are unstable, have high and/or complex injuries, have an open incision, and those who have suspected severe inflammation. Long-term outcomes data is required to better understand this question. *(Expert opinion)*

Summary of the evidence

One comparative, retrospective study was included in this analysis. It addressed the outcomes of stricture, endoscopic re-intervention, and cholangitis with high risk of bias due to selection bias and lack of statistical control for confounding variables [65].

Benefits

MIS repair was better than open surgical repair across the following outcomes:

- re-intervention—endoscopic/radiologic (1 observational study with 20 participants, very low certainty of evidence, OR 0.25, CI [0.01–6.82], 81 fewer per 1000, CI [110 fewer to 349 more])
- Stricture (1 observational study with 20 participants, very low certainty of evidence, OR 0.13, CI [0.01–3.11], 186 fewer per 1000, CI [219 fewer to 248 more])
- Cholangitis (1 observational study with 20 participants, very low certainty of evidence, OR 0.13, CI [0.01–3.11], 186 fewer per 1000, CI [219 fewer to 248 more])

The combined magnitude of these effects was determined to be large.

Harms and burden

MIS repair did not demonstrate any outcomes associated with greater harm than open surgical repair.

The combined magnitude of these effects was determined to be trivial.

Certainty of evidence

The overall certainty of evidence was very low due to the high risk of bias in the single study included, the imprecision present for each outcome, and the serious indirectness. The indirectness was attributed to the fact that all patients in the study had the BDI detected during the index cholecystectomy. This, therefore, does not encompass the full breadth of the population of interest as postoperative detection of BDI is common and requires a separate anesthesia event and additional decision making. Lastly, imprecision was considered due to the small sample size (20 patients).

Evidence discussion to final recommendation

Evidence tables and EtD judgements can be found in Appendix A and B, respectively. The final recommendation was made with consideration of patient values, global acceptability and feasibility. While MIS repair would likely be acceptable to stakeholders, there may be concerns for the feasibility in rural, under-resourced areas, or those without the expertise required for the procedure.

The panel unanimously agreed that MIS repair of BDI is a reasonable and, perhaps favorable, option compared to open surgery. In particular, robotic assisted repairs may provide the range of motion, enhanced dexterity, and a wide, stable 3D visual field. Ultimately, however, there is little data to drive this discussion. Furthermore, important outcomes such as quality of life and return to the operating room due to failure were not investigated.

Trepidation may surround MIS repairs due to entering a reoperative abdomen with underlying adhesions, but entering the abdomen away from the index incision sites is typically safe. Laparoscopic repairs, when compared to robotic assisted repairs, may require significantly more expertise to ensure that the benefits outweigh the risks of open surgery. There is often extensive inflammation in the area of injury, especially more than a week from the index operation. This can limit the ability to perform MIS repairs. Specifically, very few surgeons have adequate experience in fine laparoscopic suturing especially in such a complex area as the portal hepatis. Robotic suturing may overcome some of these challenges.

Ultimately, MIS repair is preferred in those patients who are stable, with favorable anatomy (initial operation performed in an MIS fashion, anatomically lower injury in the biliary tree, absence of associated vascular injury) and in those with high BMI or obesity as it can facilitate exposure and provide better visualization compared to open surgery. Open surgery is preferred in those that are unstable, have high and/or complex injuries, have an open incision, and those who have suspected severe inflammation. These attributes, as well as surgeon experience in either method, should be taken into consideration when deciding which operative approach to pursue, in addition to the intraoperative versus delayed recognition of the injury.

Conclusion

The panel suggests either MIS or open surgery in the definitive repair of BDI following cholecystectomy. The patient's stability, anatomy, and BMI as well as surgeon expertise are critical considerations when making this decision.

Future research recommendations

Future research considerations include the need for a large multicenter registry study with matched cohorts. Quality of life, an important patient value, should also be prioritized as an outcome in future studies. Randomized data would be very difficult to obtain due to selection bias when choosing the operative approach. Variables such as associated vascular injury, severity of injury, duration of injury, presence of sepsis, attempt at previous repair and the presence of temporizing measures prior to repair should all be documented in registries and analyzed in future studies. In addition, economic analysis studies comparing the two approaches would also be useful for future updates of this recommendation.

KQ 3: Should patients with a known bile duct injury undergo definitive operative management or nonoperative management?

Recommendation: The panel suggests either definitive operative management or nonoperative management for amenable injuries with expertise available. *(conditional recommendation, very low certainty of evidence)*

Summary of the evidence

There were 8 observational studies included in this analysis [65–72]. Seven had high risk of bias due to selection bias and lack of statistical control for possible confounding variables. One study, Pitt et al., was low risk of bias and had an even distribution of Strasberg classified injury (ranging from Strasberg B to E) between both groups [67]. This study only provided one outcome, stricture, but it was about 40% of the weight in the meta-analysis amongst 7 other studies. All data compared endoscopic therapy versus surgery, which included all repair techniques.

The evidence demonstrated that nonoperative management was preferred in the outcomes of mortality and cholangitis, but these had very low certainty of evidence and very wide confidence intervals and should be considered with caution. Operative repair was favored in the outcomes of surgical re-intervention, endoscopic/radiologic re-intervention, and stricture. Surgical re-intervention and stricture had low certainty of evidence, providing slightly more reliability.

Benefits

Nonoperative repair was better compared to operative repair across the following outcomes:

- Cholangitis (1 study with 24 participants, very low certainty of evidence, OR 0.82, CI [0.03–20.30], 16 fewer per 1000, CI [97 fewer to 593 more])
- Mortality (3 studies with 172 participants, very low certainty of evidence, OR 0.18, CI [0.03–1.10], 66 fewer per 1000, CI [79 fewer to 7 more])

The combined magnitude of these effects was determined to be large.

Harms and burden and certainty of the evidence

Nonoperative repair was worse than operative repair across the following outcomes:

- re-intervention—surgery (3 observational studies with 185 participants, low certainty of evidence, OR 16.6, CI [2.28–120.9], 416 more per 1000, CI [57 more to 814 more])
- re-intervention—endoscopic/radiologic (2 observational study with 41 participants, very low certainty of evidence, OR 2.09, CI [0.2–22.29], 36 more per 1000, CI [28 fewer to 417 more])
- Stricture (8 observational study with 538 participants, low certainty of evidence, OR 2.44, CI [1.45–4.09], 116 fewer per 1000, CI [40 more to 217 more])

The combined magnitude of these effects was determined to be large.

Certainty of evidence

The overall certainty of evidence was very low.

Evidence discussion to final recommendation

Evidence tables and EtD judgements can be found in Appendix A and B, respectively. The final recommendation was made with consideration of patient values, global acceptability and feasibility. While endoscopic repair would likely be acceptable to stakeholders, there may be concerns for the feasibility in rural, under-resourced areas, or those without the expertise required for the procedure.

When considering nonoperative versus operative repair for the definitive management of BDI, severity of injury and expertise availability are at the forefront of discussion. Endoscopic management of severe BDI injuries lends itself to Type D injuries and lower E1, E2 injuries, although it can technically be performed in all types. Most studies had high selection bias because of this. Even in the low risk of bias study, surgical intervention was favored in Type E3 and E5 injuries while endoscopy was favored in C, D, and E1 injuries, although both therapies were used across all injury types. Thus, only select centers would have the expertise to treat the more complex injuries endoscopically, while most would be able to treat Type D injuries should they have access to endoscopists. Furthermore, favorable anatomy with a dilated biliary system is typically needed in these patients and those with prompt discovery of the injury may not be as good of candidates for endoscopic intervention for this reason.

The data presented demonstrate better outcomes for endoscopic therapy with regard to mortality and cholangitis, and better outcomes for operative therapy with regard to stricture rates, endoscopic/radiological re-intervention, and surgical re-intervention. However, this was difficult to incorporate into decision-making because mortality data were based on three studies all with high risk of bias and may not be an accurate representation. Specifically, there was significant selection bias and it is likely that the severity of the injury played a major role in the higher mortality rates seen in the surgical group. In addition, there were fewer re-interventions and lower stricture rates for the operative group, and this had a higher certainty of evidence.

While recommendations for operative therapy were considered, the panel ultimately agreed that if the expertise is available and it is safe for the patient, an endoscopic attempt at managing the BDI is reasonable, given that it is associated with lower mortality rates. This should only be done at select centers with advanced endoscopic expertise if the injury is complex.

Patients generally felt that preserving quality of life and limiting the amount of time and number of interventions for treatment was most important, although they agreed that all outcomes were important. In addition, they preferred to return to their lives as quickly as possible and minimize pain. Endoscopic management often requires several re-interventions for months at a time to fully treat the injury and is therefore potentially less desirable. Setting expectations with patients about the need for re-interventions, complications, and hospital stays with both endoscopic therapy and operative therapy is of utmost importance as this could largely influence their decision to favor one strategy over the other.

Conclusion

The panel suggests that in less severe injuries with a dilated biliary system, nonoperative techniques may be favored. In contrast, an operative approach may be favored in those with a decompressed biliary system, severe sepsis, and complex biliary or vascular injury. Other factors to consider include the nature of the injury, available expertise, and patient preference.

Future research recommendations

Future research should focus on a large multicenter RCT in non-septic, stable patients comparing operative and nonoperative management with stratification of outcomes by injury type. There is a need for cost-effectiveness analysis comparing alternatives. Further, endoscopic management of complex injuries is a challenge and can only be done at select centers; an implementation study investigating what is needed to launch such a program is critical. More data is also needed on the role of nonoperative IR management, specifically in higher grade injuries. Finally, outcomes from high volume centers in endoscopic and IR treatment would be helpful, as well as data investigating quality of life.

KQ4: Should patients with known bile duct injury undergoing surgery be repaired using hepaticoduodenostomy or hepaticojejunostomy?

Recommendation: The panel suggests either hepaticoduodenostomy or hepaticojejunostomy with the decision dependent upon location of injury and expertise of the surgeon. *(conditional recommendation, very low certainty of evidence)*

Long-term outcomes data is required to better understand this question.

Summary of the evidence

There were 2 observational studies in this analysis, both with high risk of bias due to selection bias and lack of statistical control for possible confounding variables. Moraca et al. was the more relevant study as this directly compared hepaticoduodenostomy (HD) to hepaticojejunostomy (HJ). Hadi et al., had data available for both modalities but this was not the aim of the study and it compared choledochoduodenostomy rather than HD to HJ [73, 74].

Evidence tables and EtD judgements can be found in Appendix A and B, respectively.

Benefits

HD was not found to have any benefits over HJ repair in this analysis.

The combined magnitude of these effects was determined to be trivial.

Harms and burden

HD was worse than HJ repair across the following outcomes:

- re-intervention—endoscopic/radiologic (1 observational study with 21 participants, very low certainty of evidence, OR 2.85, CI [0.13–64.89], 141 more per 1000, CI [86 fewer to 778 more])
- Stricture (2 observational studies with 47 participants, very low certainty of evidence, OR 1.59, CI [0.16–15.40], 23 more per 1000, CI [35 fewer to 359 more])

The combined magnitude of these effects was determined to be large.

Certainty of evidence

The overall certainty of evidence was very low.

Evidence discussion to final recommendation

Evidence tables and EtD judgements can be found in Appendix A and B, respectively. The final recommendation was made with consideration of patient values, global acceptability and feasibility. HD and HJ are likely considered acceptable and feasible provided the surgical expertise is available to perform either, which is expected in those surgeons performing these types of repairs.

Bilioenteric anastomosis is a well-established option for surgical repair of BDI following cholecystectomy. HJ is widely performed but is technically more challenging than HD. HJ is typically performed for more proximal, higher injuries and requires two anastomoses (the HJ and the jejunojejunostomy). Furthermore, it can be extremely challenging in patients with obesity, those who have a short mesentery, those with congenital aberrant anatomy or those with previous enteric bypass and/or abdominal surgery with extensive intra-abdominal adhesions. In comparison, HD offers the benefit of being more physiological and provides easier access to the repair if an evaluation is needed postoperatively using cholangiography or endoscopy. Conversely, HD can be challenging if there is substantial inflammation in the porta hepatis, making mobilization of the duodenum potentially unsafe. In addition, the higher the injury, the more mobilization is required for creation of a tension-free HD anastomosis, whereas this is usually not the case with HJ. Contraindications to HD repair include those patients with E5 injuries or severe pancreatitis. One must also consider the potential long term complications with HD repair including sump syndrome and alkaline reflux.

Timing of surgery is also an important consideration as those with biliary sepsis may benefit from a less complex surgery via HD.

The decision between the two approaches is largely based on location of the injury, patient characteristics, and technical expertise as some surgeons have more experience in one over the other. This is again under the assumption that the patient has been referred to an expert in biliary surgery. Ultimately, it is important for surgeons to know how to do both reconstructions given the many individual considerations previously described favoring one approach over the other.

Conclusion

The panel suggests either HD or HJ for bilioenteric repair of BDI following cholecystectomy. Patient characteristics, location of injury, and the expertise of the surgeon are important factors to consider in decision making.

Future research recommendations

Future research considerations are critical as there is a large paucity of data regarding outcomes for HD. Data that support HD are important as an HJ may be less favorable or unsafe in select patients. High quality observational studies are needed comparing the two modalities. RCTs may be prohibitively challenging given the many patient and scenario-specific factors determining the optimal operative approach. Investigating longer term outcomes and quality of life should also be incorporated in future studies.

Discussion

Implementation of these guidelines

The SAGES Guidelines Committee has several mechanisms for distribution and dissemination of these guidelines to key stakeholders (e.g. surgeons, patients). The guidelines will be announced in the electronic SAGES newsletter. They will be published in the journal *Surgical Endoscopy* which is free for all SAGES members and the guidelines will be posted on

the SAGES website. The guidelines will also be summarized in a visual abstract and published on the aforementioned platforms as well as on social media.

Monitoring and evaluation

Monitoring and evaluation after the implementation of these guidelines is critical to improve upon the current data and to make the modifications necessary for each institution. In general, outcomes of interest to the surgeon and patient should be compared before and after implementing delayed surgical repair, nonoperative management, and hepaticoduodenostomy. All outcomes discussed in this guideline for each surgical application should be recorded for patients who undergo BDI repair. In particular, 5–10 year data with respect to stricture rate, quality of life, mortality, and re-intervention (surgical or otherwise) for all types of BDI repair would be of substantial importance.

Health equity

Health equity must be considered as countries, regions, and populations have different lived-experiences, expertise, and resources. For these reasons, it was taken into account during the evidence-to-decision guideline creation process. Hospitals with limited resources and availability of surgical expertise may be more limited in their options regarding timing and type of BDI repair. Furthermore, minimally invasive equipment, especially robotic platforms, is not present in all facilities, limiting the ability to perform MIS repairs. Endoscopic and IR specialists may not exist or may not be well versed in the specific therapies required to treat BDI nonoperatively, also limiting the options available in those institutions. Finally, these guidelines were made through a lens that patients were being surgically treated by a surgeon well versed in hepatobiliary surgery. These limitations may be seen in rural or community settings or in settings with limited ability to transfer patients to a higher level of care. With this in mind, providers are asked to consider their local resources and make decisions that reflect the safest option for their patients.

What others are saying

The World Society of Emergency Surgery (WSES) created guidelines addressing seven key questions in 2021 for the management of BDI during cholecystectomy in 2020 [75]. The final key question overlaps with our current guideline and addresses the surgical management of BDI and timing of repair. Importantly, while they performed a comprehensive literature search and summarized it, they did not conduct a systematic review or meta-analysis. However, they had a more diverse group of panelists including anesthesiologists, gastroenterologists, hepatologists, and radiologists in addition to surgeons. Several of their guidelines within the relevant key question addressed minor BDIs, which were not discussed in our guideline. Regarding major BDIs, they also recommended a later definitive repair of at least three weeks, with interim interventions for management of sepsis, if the patient presented between 72 h and 3 weeks from injury. Their recommendations differ slightly in that they recommend Roux-en-Y hepaticojejunostomy for presentation with late stricture. While we do not disagree with this in our guidelines, we also propose endoscopic interventions and hepaticoduodenostomy as definitive repair in select cases. Overall, there is agreement between the guidelines but their question is vague and the lack of meta-analysis, provides a more nebulous approach to interpretation of the data.

The European Association for Endoscopic Surgery (EAES) created a set of guidelines in 2011 addressing BDI during cholecystectomy [76]. A systematic literature search was performed, however, no metanalysis was performed and no clear system for appraisal of the literature was described. This guideline, similar to WSES, discusses several elements of BDI including prevention and diagnosis. The final set of key questions, which addressed management, did not address specifics but rather made statements reporting that major BDI management should be left to an expert and depends on the experience and the type of injury. We would generally agree with this statement, however, our guideline provides a metanalysis, more recent review of the literature and addresses specific interventions and comparators regarding the definitive repair of BDIs.

Updating these guidelines

These guidelines will be managed and reevaluated for update every three years by the Guidelines Update Task Force (GUFT) according to the protocol criteria [77]. The guidelines will be reevaluated at an earlier time if new data necessitates an earlier update.

Limitations of these guidelines

Each recommendation had a very low certainty of evidence, limiting their interpretation. Further, BDI is highly variable, and selection bias and the presence of confounding factors are inevitable. Not all injuries can be treated the same way and the surgeon (along with a multidisciplinary team) should decide which modality is safest and most effective. Ideally each outcome could be stratified by degree of injury but this

was not possible with the data available. Furthermore, concomitant vascular injury could not be analyzed as a subgroup due to the lack of outcomes specific to this group, though it is clear that its presence could influence the outcomes and the type of therapy chosen. Finally, this panel had limited experience with definitive endoscopic interventions which may have influenced voting and discussion for KQ3.

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